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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,384	01/16/2007	Alastair David Griffiths Lawson	CELL-0315	1913
20306 7590 07/10/2009 MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606				
EXAMINER GAMBEL, PHILLIP				
ART UNIT 1644		PAPER NUMBER		
MAIL DATE 07/10/2009		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/578,384

**Applicant(s)**

LAWSON ET AL.

**Examiner**

Phillip Gambel

**Art Unit**

1644

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-25 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 20 and 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 15-19 and 21-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### DETAILED ACTION

1. Applicant's amendment, filed 04/21/2009, has been entered.

Claims 15-17 have been amended.

Claims 1-11 have been canceled previously.

Claims 12-25 are pending.

Claims 12, 15-19 and 21-22 are under consideration as they read on treating inflammatory bowel disease (e.g., ulcerative colitis and Crohn's disease) with anti-CSF-1 antibody (i.e., anti-M-CSF antibody) as they read on the elected invention and species.

Claims 13-14, 20 and 23-25 have been withdrawn from further consideration by the examiner as being drawn to a nonelected inventions and/or species.

The examiner notes claim 12 was inadvertently included in this section on withdrawn claims.

The examiner apologizes for any inconvenience to applicant in this matter.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Office Action will be in response to applicant's amendment, filed 04/21/2009.

The rejections of record can be found in the previous Office Action, mailed 12/10/2008.

3. The previous rejection under 35 U.S.C. § 112, second paragraph, with respect to the recitation of "or a functionally active antibody or derivative" has been withdrawn in view of applicant's amended claims, filed 04/21/2009.

4. The previous objection to the claims has been withdrawn in view of applicant's amended claims, filed 04/21/2009.

5. Claims 15-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-19 stand indefinite in the recitation of "or a functionally active antibody or derivative" as well as "epitope binding fragment" because the claims are ambiguous.

It appears that the "epitope binding fragment" is intended to read on "CSF-1 antigen binding fragments thereof". However, the claims currently read on any "epitope binding fragment".

For clarity, applicant is invited to replace "epitope binding" with "CSF-1 binding fragments"

As indicated previously for the record, it appears that “derivative” is intended to read on the polymers disclosed on pages 10-11 of the instant specification, and not on “derivatives” as they might read on modifying antigen specificity of the claimed antibodies.

Again, applicant is invited to amend the claims to clearly recite the intended “antigen-binding fragments” and to clarify the metes and bounds of the intended “derivatives”.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

6. The previous rejection under 35 U.S.C. § 112, first paragraph, enablement with respect to the recitation of “prophylaxis” has been withdrawn in view of applicant’s amended claims, filed 04/21/2009.

7. Claims 12, 15-19 and 21-22 are rejected under 35 U.S.C. § 102(e) as being anticipated by over Bedian et al. (US 2005/0059113) (see entire document)

and as further evidence that CSF-1 is also known as M-CSF at the time the invention was made, as acknowledged on page 1, paragraph 2 of the instant specification essentially for the reasons of record.

Applicant’s arguments, in conjunction with Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc., 88 USPQ2d 1381 (Fed. Cir. 2008), filed 04/21/2009, have been fully considered but have not been found convincing essentially for the reasons of record.

When the species is clearly named, the species claim is anticipated no matter how many other species are additionally named

See Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990).

Also, see MPEP 2131.02.

A reference contains an enabling disclosure if the public was in possession of the claimed invention before the date of invention. Such possession is effected if one of ordinary skill in the art could have combined the publication’s description of the invention with his or her own knowledge to make the claimed invention .

See In re Donohue, 226 USPQ 619 (Fed. Cir. 1985).

Also, see MPEP 2121.01.

The proper issue is whether the prior art is enabling in the sense that it describes the claimed invention sufficiently to enable a person of ordinary skill in the art to carry out the invention.

For example, see Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc., 81 USPQ2d 1001 (Fed. Cir. 2006).

With respect to applicant's reliance on Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc., 88 USPQ2d 1381 (Fed. Cir. 2008),

Bedian et al. is directed to anti-M-CSF antibodies and not to a particularly large number of compounds (as found in Impax)

along with clear teachings of making and using antagonistic anti-M-CSF antibodies (e.g., see paragraphs [0098] – [0102], [0180], 0222] – [0223], [0236]–[0237] ),

along with clear teachings of providing effective amounts and dosage regimens that can be adjusted to the individual need and the professional judgment of the person administering or supervising the administration (e.g., see paragraph [0260] - [0262] ),

along with the clear teaching of treating Crohn's disease and ulcerative colitis (e.g., see paragraph [0249] );

as well as Examples of making and using antagonistic anti-M-CSF antibodies in in vitro and in vivo assays (e.g., see Examples I- X on pages 29-33).

The prior art teaching is consistent with applicant's own disclosure that inhibitors of CSF-1 activity were well known in the art as were the methods of identifying and producing such inhibitors (e.g., see page 4, paragraph 2 of the instant specification), techniques were known to physicians familiar with IBD that could be used to determine whether a candidate agent has altered one or more symptoms associated with the disease (e.g., see page 14, paragraph 3 of the instant specification) and that the dosage to be administered of CSF-1 activity will vary according to the particular inhibitor, the type of IBD, the subject and the nature of severity of the disease and the physical condition of the subject, which can be readily determined by the person skilled in the art (e.g., see page 18, paragraph 6 of the instant specification).

The issue of enablement under 35 USC 102 is a question of whether one of ordinary skill in the art would know how to make and use the invention based on the reference's disclosure and that the standard for enablement of a prior art reference for purposes of anticipation under 102 differs from the enablement standard under 35 USC 112.

See In re Gleave, 90 USPQ2d 1235, 1238 (Fed. Cir. 2009).

In contrast to applicant's arguments, the prior art clearly teaches the claimed methods in a manner for the ordinary person to practice or carry out the claimed methods of treating IBD with anti-M-CSF antibodies.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 145 USPQ 716, 718 (CCPA 1965).

The following is reiterated for applicant's convenience.

Bedian et al. teach methods of treating various conditions encompassing inflammatory bowel disease, Crohn's disease and ulcerative colitis (e.g., see paragraph [0249] ), with anti-M-CSF antibodies, including antibody fragments (e.g., see paragraphs [0098] – [0102], [0180], 0222] – [0223], [0236]–[0237] ), therapeutic conjugates thereof (e.g., see paragraphs [0127] – [0128], [0241] – [0246]) and biocompatible polymers thereof (e.g., derivatives; e.g., see paragraph [0255] ) (see paragraphs [0098] - [0246], [0247] – [0263]).

Applicant's arguments have not been found persuasive

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/  
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Art Unit 1644  
July 8, 2009

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